IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**24-md-3094**
THIS DOCUMENT RELATES TO:	:	
	:	**HON. KAREN SPENCER MARSTON**
ALL ACTIONS/ALL CASES	:	**Filed Conditionally Under Seal Pursuant to Order Re: Filing Documents Under Seal ECF 187-2**

PLAINTIFFS' BRIEF IN SUPPORT OF ITS MOTION TO SUPPLEMENT THE RECORD AS TO CROSS CUTTING ISSUE NO. 1

Come the Plaintiffs, through Co-Lead Counsel, and for their brief in support of their motion to supplement the record as to cross cutting issue no. 1[1] state as follows:

Although Lilly has taken the position with this Court that a gastric emptying study is necessary to reliably diagnose gastroparesis, [redacted]. In August 2023, the FDA requested that "[redacted]."[2] In its response submitted to the FDA in October 2023, [redacted]

[1] Cross cutting issue no. 1 pertains to the reliable diagnosis of gastroparesis and whether a gastric emptying study is necessary for the diagnosis of gastroparesis. *See* CMO 18, ECF 235 (Aug. 23, 2024).
[2] *See* **Exhibit 1:** Lilly Regulatory Response at LLY-GLPMDL-08233975 (Oct. 2, 2023).

[redacted][3]

[redacted]

Therefore, Plaintiffs move to supplement the record from the May 14, 2025 hearing on cross cutting issue no. 1 with the attached Exhibit 1 (Lilly's Oct. 2, 2023 Response to the FDA) with the pertinent portion located at LLY-GLPMDL-08233982. Although this document was produced prior to the May 14, 2025, hearing as part of Lilly's voluminous document production, Plaintiffs only recently identified these statements relevant to cross cutting issue no. 1 during extensive preparation that is currently occurring for numerous upcoming depositions of Lilly personnel.[4] [redacted] go to the heart of cross cutting issue no. 1, and as a result, Plaintiffs believe it is important that the Court consider these statements. Indeed, where a party has "made a statement to a regulatory agency" and that party takes a position in court contrary "to one presented to the regulatory agency," that party may be appropriately estopped from taking a position different than that presented to the agency.[5] [redacted]

[3] *See* **Exhibit 1:** Lilly Regulatory Response at LLY-GLPMDL-08233982 (Oct. 2, 2023) (emphasis added).

[4] As Plaintiffs have previously argued, further discovery is likely to yield additional relevant evidence that will be helpful in resolving cross cutting issue no. 1. *See, e.g.,* Plaintiffs' Letter Brief, ECF 303 at n.4 (Dec. 11, 2024) ("Plaintiffs' counsel continue to believe that discovery will uncover evidence relevant to Issue No. 1.").

[5] *Brian Handel D.M.D., P.C. v. Allstate Ins. Co.,* 499 F. Supp. 3d 95, 101 (E.D. Pa. 2020) (citing *Hussey Copper, LTD v. Arrowood Indem. Co.,* 391 F. App'x 207, 211 (3d Cir. 2010); *Simon Wrecking Co., Inc. v. AIU Ins. Co.,* 541 F. Supp. 2d 714, 717 (E.D. Pa. 2008) ("reliance is not a required element of regulatory estoppel"); *see also In re Suboxone,* 2017 WL 4810801, at *9 (E.D. Pa. Oct. 25, 2017) (recognizing that regulatory estoppel may apply to drug manufacturer based on statements to regulatory agency but declining to apply the doctrine where plaintiffs failed to identify the statements made to regulators).

[redacted].

WHEREFORE, Plaintiffs respectfully request that the attached Exhibit 1 be considered by the Court in making any determinations as to cross cutting issue no. 1.

Dated: July 23, 2025

Respectfully submitted,

/s/ Paul J. Pennock

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CERTIFICATE OF SERVICE

I hereby certify that on July 23, 2025, a true and correct copy of the foregoing document was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

/s/ Paul J. Pennock
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